Registration Decision RD2010-19

3-Methyl-2-Cyclohexen-1-One (MCH Technical)

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Registration Decision for 3-Methyl-2-Cyclohexen-1-One (MCH Technical)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of MCH Technical and MCH Bubble Cap, containing the technical grade active ingredient 3-Methyl-2-Cyclohexen-1-One, to deter Douglas-fir beetle, *Dendroctonus pseudotsugae*, and spruce beetle, *Dendroctonus rufipennis*, from attacking Douglas-fir trees and spruce trees, respectively.

MCH Technical (Registration Number 28638) and MCH Bubble Cap (Registration Number 28637) are conditionally registered in Canada. Although the risks and value of MCH Technical have been found to be acceptable when all risk-reduction measures are followed, the applicant was required to submit additional scientific information as a condition of registration. The additional information included acute toxicity studies to properly characterize the toxicological hazards of MCH Technical and additional environmental toxicity studies to determine the effect of MCH Bubble Cap on birds. The current applications were submitted to convert MCH Technical and MCH Bubble Cap from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-17, *3-Methyl-2-Cyclohexen-1-One (MCH Technical)*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for 3-Methyl-2-Cyclohexen-1-One and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-17. This decision is consistent with the proposed registration decision stated in PRD2010-17.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-17, *3-Methyl-2-Cyclohexen-1-One (MCH Technical)* that contains a detailed evaluation of the information submitted in support of this registration.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is MCH?

MCH is an anti-aggregation pheromone for both the Douglas-fir beetle and the spruce beetle. This pheromone is released by the beetles after they successfully attack a host tree. When released in sufficient quantities, MCH signals to any incoming beetles that a host tree is already fully occupied thereby deterring additional beetles from attacking the tree because they would not be able to reproduce successfully due to competition from the other beetles already established in the tree. MCH Bubble Cap is applied by stapling individual bubble caps to trees or stumps.

Health Considerations

Can Approved Uses of MCH Affect Human Health?

MCH is unlikely to affect your health when used according to label directions.

Exposure to MCH may occur when handling and applying the product, as well as recovering used and dislodged MCH Bubble Caps. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human

[3] "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

[4] "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Since the technical grade active ingredient, MCH, is slightly acutely toxic in animal studies, the statement, "CAUTION – POISON", has been included on the principal display panel of both the general label and the individual MCH Bubble Cap label, and "Harmful if swallowed" and "Avoid breathing vapours" have been included in the PRECAUTIONS section of the secondary display panel of the general label.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The proposed use pattern of MCH Bubble Cap is for non-food situations. Therefore, the use of MCH is not expected to result in dietary risk from food and/or water.

Occupational Risks From Handling MCH

Occupational risks are not of concern when MCH is used according to label directions, which include protective measures.

Pesticide applicators and workers handling and attaching MCH Bubble Caps to Douglas-fir and spruce trees can come in direct contact with MCH on the skin and eyes, if the bubble caps are punctured or improperly sealed. The current label statements adequately mitigate the concern of exposure to the applicators or workers.

Any potential for inhalation of MCH while handling and applying the product is anticipated to be negligible, if the precautionary statements are observed.

Accidental bystander exposure is possible in situations where the bubble cap has been dislodged from the tree and punctured by adults, children, and/or companion animals. Exposure is expected to be negligible, if the precautionary label statement, "Keep out of reach of children and pets", is observed, the bubble cap is properly affixed to the tree, and each individual bubble cap has its own precautionary labelling. Every bubble cap label includes the following information:

> "MCH Bubble Cap
>
> Registration No. XXXXX PCPA
>
> CAUTION POISON [poison symbol]
> EYE AND SKIN IRRITANT
>
> DO NOT puncture bubble caps or handle their contents
>
> Phero Tech International Inc. (604) 940-9944

The bubble caps are expected to be depleted of MCH (3-methyl-2-cyclohexen-1-one) within 50 days of application. Removal of the spent bubble caps will not result in any significant post-application exposure to the worker."

Environmental Considerations

What Happens When MCH Is Introduced Into the Environment?

MCH is a highly volatile insoluble anti-aggregation pheromone that is naturally present in the environment at levels higher than the proposed application rate and is not expected to cause any adverse effects to non-target organisms.

MCH is an anti-aggregation pheromone for the Douglas-fir beetle and the spruce beetle. MCH is also a relatively common chemical produced by some animals, found in a variety of food products, and is approved by the FDA as a food additive. MCH bubble caps are slow release plastic pouches containing the active ingredient MCH. MCH bubble caps are attached to standing and fallen Douglas-fir and spruce trees and stumps, and stands containing Douglas-fir or spruce trees. MCH Bubble Cap deters mass attack by the target pests.

MCH is highly volatile and insoluble in water, therefore, it is not expected to leach into ground water or be persistent in water or soil. However, being highly volatile, non-target organisms could be exposed in the air or by direct consumption of the content of the bubble caps. The exposure of non-target terrestrial organisms to MCH under operational conditions is considered to be negligible. MCH is unlikely to bioaccumulate under neutral conditions. MCH has no dissociable moities.

Value Considerations

What Is the Value of MCH Bubble Cap?

MCH, an anti-aggregation pheromone, deters Douglas-fir beetle and spruce beetle from attacking Douglas-fir trees and spruce trees, respectively.

Application of MCH Bubble Cap to Douglas-fir trees and spruce trees deters Douglas-fir beetle and spruce beetle from attacking and killing these trees. Application of MCH Bubble Cap to fallen trees and stumps deters the beetles from infesting these preferred host materials and thereby prevents beetle populations from increasing to levels that threaten healthy trees.

No other pest control products are currently registered for use against either Douglas-fir beetle or spruce beetle to protect trees from attack.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of MCH Bubble Cap to address the potential risks are as follows.

Key Risk-Reduction Measures

Human Health

There is a possibility of oral, dermal, and inhalation exposure by workers and bystanders, particularly children and pets, coming into direct contact with dislodged, punctured, or improperly sealed MCH Bubble Caps. Individuals must wash their hands with soap and water after handling, as well as remove any contaminated clothing. Individuals should avoid skin contact and inhalation of the contents of the bubble caps. Children and pets should not be permitted in and around areas where the MCH Bubble Caps have been applied.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra infoserv(*a*)hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra infoserv(*a*)hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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Reference: 2006, DACO 2-chemistry for TGAI, N/A, MRID: N/A, DACO: 2.0, 2.1, 2.12, 2.12.1, 2.12.2, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9

PMRA Document Number: 1304791
Reference: 2006, Manufacturing Methods and Preliminary Analysis for 3-Methyl-2-Cyclohexenone, N/A, MRID: N/A, DACO: 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4

PMRA Document Number: 1304795
Reference: 1999, Additional properties information on Cyasorb UV-5411, N/A, MRID: N/A, DACO: 2.16

PMRA Document Number: 1304796
Reference: Patrick Durkin, 2001, Syracuse Environmental Research Associates, Inc., MCH WordPerfect Worksheets for Human Health and Ecological Risk Assessments, N/A, Syracuse Environmental Research Associates, Inc., MRID: N/A, DACO: 2.16

PMRA Document Number: 1304823
Reference: 2006, DACO 3: specifications for EP, N/A, MRID: N/A, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.3.1, 3.4.2, 3.5, 3.5.2, 3.5.4, 3.5.5, 3.5.6

PMRA Document Number: 1304824
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2.0 Human and Animal Health

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PMRA Document Number: 1304803
Reference: 2006, DACO 4.5.2 and 4.5.3: rat developmental and rabbit developmental studies - waiver request, DACO: 4.5, 4.5.2, 4.5.3

PMRA Document Number: 1304804
Reference: 2006, DACO 4.5.4, 4.5.5 and 4.1.5.6: genotoxicity studies - waiver request, DACO: 4.5, 4.5.4, 4.5.5, 4.5.6

PMRA Document Number: 1304805
Reference: 2006, Joint Expert Committee on Food Additives UN-WHO: Alicyclic ketones, DACO: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.8

PMRA Document Number: 1304806
Reference: 1998, MCH Human Health and Ecological Risk Assessment: Final Report, prepared for USDA Forest Service, DACO: 4.2.1,4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.8, 9.9

PMRA Document Number: 1304831
Reference: 2006, DACO 5: Exposure (occupational and bystander) (EP), DACO: 5.2

PMRA Document Number: 1584737
Reference: 1976, Acute oral toxicity in rats, eye irritation in rabbits, inhalation toxicity in rats, DACO: 4.2.1, 4.2.3, 4.2.4

PMRA Document Number: 1584738
Reference: 2008, Request for data waivers of 3-methyl-2-cyclohexen-1-one (MCH) on dermal toxicity, DACO: 4.2.2, 4.2.5, 4.2.6

3.0 Environment

PMRA Document Number: 1304808
Reference: 2006, 3-Methyl-2-cyclohexene-1-one: a dietary LC_{50} study with the northern bobwhite. Wildlife International, Ltd. Project No. 626-101. Submitted to Phero Tech Inc., Delta, BC. Study Initiation Date July 12, 2006. Study Completion Date September 14, 2006

PMRA Document Number: 1304829
Reference: 1998, MCH Human Health and Ecological Risk Assessment: Final Report, prepared for USDA Forest Service, N/A, MRID: N/A, DACO: 9.6.2.1, 9.6.2.2, 9.6.2.4, 9.6.2.5, 9.6.4, 9.9

PMRA Document Number: 1304830
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PMRA Document Number: 1589471
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PMRA Document Number: 1589472
Reference: 2008, Letter to Alan Vaudry March 31, 2008, N/A, MRID: N/A, DACO: 9.6.4

PMRA Document Number: 1589473
Reference: 2008, Letter to Alan Vaudry March 31, 2008, N/A, MRID: N/A, DACO: 9.6.4

PMRA Document Number: 1589474
Reference: 2008, Letter to Alan Vaudry April 9, 2008, N/A, MRID: N/A, DACO: 9.6.4

PMRA Document Number: 1589475
Reference: 2008, DACO 9.6.4 Laboratory Studies - Feeding Study (Birds) with End-Use Product - Request for Waiver, N/A, MRID: N/A, DACO: 9.6.4

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Reference: Borden, J., 1982, Aggregation pheromones; Borden, J., Bark Beetles in North American Conifers, A system for the Study of Evolutionary Biology, Number Six, The Corrie Herring Hooks Series, University of Texas Press, Austin, pg. 75-139, N/A, MRID: N/A, DAC

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4.0 Value

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PMRA Document Number: 1304843
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